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PATENTS

MAILING CERTIFICATION

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Bruce S. Londa

PTTB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty's Docket No: 101195-65

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Examiner : TBA

Group Art Unit TBA

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JUL 26 2002

Applicant : Stefan Anker, et al.

AUG 08 2002

TECH CENTER 1600/29C

Appln. No. : 10/019,452

TECH CENTER 1600/2900

Filed : February 25, 2002

For : Therapy and Use of Compounds in Therapy

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Hon. Assistant Commissioner of Patents
Washington, D.C. 20231

Dear Sir:

The following sections are being submitted for this Information

Disclosure Statement:

- Sec. 1 - Preliminary Statements
- Sec. 2 - Identification of Time of Filing
- Sec. 4 - Statements with Respect to Listing of Information
- Sec. 5 - Statements with Respect to Translations of Non-English Information
- Sec. 6 - Statements with Respect to Copies of Listed Information Items Accompanying This Statement
- Sec. 8 - Concise Explanation of Listed Information Items

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Section 1
Preliminary Statements

Applicants submit herewith patents, publications or other information of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR 1.56.

While this Information Disclosure Statement may be "material" pursuant to 37 CFR 1.56 it is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(b) the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists.

Section 2
Identification of Time of Filing

This Information Disclosure Statement is filed before the issuance of the first office action.

The art was cited in the specification of the present application.

Section 4
Statements with Respect to Listing of Information

A list of the patent(s) and/or publications is set forth on the attached pages of Form PTO-1449 (modified).

a) U.S. patent no. 5,858,998 in the English language is believed to be the equivalent of German patent 197 17 252.

Section 5
Statements with Respect to Translations of
Non-English Information

No English language translations of the foreign language patents, publications or information or parts thereof are readily available.

Section 6
Statements with Respect to Copies of Listed Information
Items Accompanying This Statement

A copy of each of the items on PTO-1449 (modified) is supplied herewith.

Section 8
Concise Explanation of Listed Information Items

A concise explanation of the items listed on PTO-1449 (modified) is given for each listed item.

German 297 17 252

U.S. patent no. 5,858,998 is believed to be an equivalent of this German patent. A copy of the U.S. patent is attached to the German patent.

PCT/EP95/04533

The invention concerns a process for preparing isoursodesoxycholic acid, wherein the ursodesoxycholic acid is first esterified and the resultant ursodesoxycholic acid ester is reacted by the Mitsunobu reaction to form isoursodesoxycholic acid ester. The isoursodesoxycholic acid ester is then saponified to form

isoursodesoxycholic acid. The process is distinguished by the simplicity with which it is carried out and the high yields and amounts in which the isorusodesoxycholic acid is obtained.

PCT/EP97/04325

A new use is disclosed of 3α -7 β -dihydroxy-5 β -cholic-24 acid (ursodeoxycholic acid, UDCA) or its derivatives to improve the immune system of HIV-infected patients, as well as in particular for preventing and treating HIV infections.

Publication (AK on page 2 of 1449)

This publication is discussed on page 3 of the present application. "Originally, UDCA was registered for the medical treatment of gallstones."... "In analogy, UDCA is used in other cholestatic disorders like primary sclerosing cholangitis." ... "Regarding its mode of action, most authorities regard increased bile flow and a reduced hepatocellular insult as a result of improved bile flow and altered bile salt patterns as the main modes of UDCA action in chronic cholestatic liver diseases."

Respectfully Submitted,



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LIST OF PATENTS AND PUBLICATIONS		Attorney Docket:	Serial No.
APPLICANT'S INFORMATION		101195-65	10/019, 31
DISCLOSURE STATEMENT (Form PTO-1449 Modified)		Applicant: Stefan Anker et al.	RECEIVED
		Filing Date: February 25, 2002	Group: JUL 26 2002 TBA
U.S. PATENT DOCUMENTS			

Examiner's Initial		Document Number	Date	Name	Class	Sub Class	Filing Date If appropriate
AA							
AB							
AC							
AD							
AE							
AF							RECEIVED
AG							AG
AH							AG
AI							AG
AJ							AG
AK							AG

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Sub Class	Translation Yes No
	AL	297 17 252	4/1998	Germany			✓
	AM	PCT/EP95/04533	6/1996	PCT			✓
	AN	PCT/EP97/04325	2/1998	PCT			✓
	AO						
	AP						

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR	U. Leuschner, et al.; "Our 10 Year Experience in Gallstone Dissolution Comparison with the National cooperative Gallstone Study (HCGS, USA) and the Tokyo Cooperative Gallstone Study (TCGS, Japan)" <i>Gastroenterology</i> 1982; 82:1113
*	AS	K. Lindor et al.; "Effects of Ursodeoxycholic Acid on Survival in Patients with Primary Biliary Cirrhosis" <i>Gastroenterology</i> 1996; 110; pgs.1515-1518
	AT	U. Beuers, et al.; "Therapie der autoimmunem Hepatitis, primär biliären Zirrhose und primär sklerosierenden Cholangitis" Konsensus der Deutschen Gesellschaft für Verdauungs- und Stoffwechselkrankheiten" <i>Z. Gastroenterol</i> 1997; 35; pgs. 1041-1049

EXAMINER:	DATE CONSIDERED:
	RECEIVED AUG 08 2002

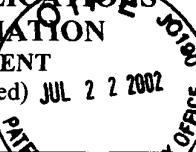
- **EXAMINER:** Initial if Reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformation and not considered, include copy of this form with next communication to applicant.

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LIST OF PATENTS AND PUBLICATIONS		Attorney Docket: 101195-65	Serial No. 10/019,452
APPLICANT'S INFORMATION		RECEIVED	
DISCLOSURE STATEMENT (Form PTO-1449 Modified) JUL 22 2002		JUL 26 2002	
		Filing Date: February 25, 2002	Group: TBA
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**U.S. PATENT DOCUMENTS**

Examiner's Initial		Document Number	Date	Name	Class	Sub Class	Filing Date If appropriate
AA							
AB							
AC							
AD							
AE							

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Sub Class	Translation Yes No
	AF			RECEIVED			RECEIVED
	AG						
	AH			AUG 08 2002			
	AI						
	AJ			TECH CENTER 1600/2900			

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AK	J. Palma et al : "Ursodeoxycholic Acid in the Treatment of Cholestasis of Pregnancy: a Randomized, Double-blind Study Controlled with Placebo" Journal of Hepatology 1997; 27; pgs. 1022-1028
AL	J. Goulis, et al ; "Randomised Controlled Trials of Ursodeoxycholic-acid Therapy for Primary Biliary Cirrhosis: a Meta-analysis" The Lancet, Vol. 354, September 25, 1999; pgs. 1053-1060
AM	M. Trauner et al.; "Review Article: Mechanisms of Action and Therapeutic Applications of Ursodeoxycholic Acid in Chronic Liver Diseases" Aliment Pharmacol Ther. 1999; 13; pgs. 979-995
AN	M. Plauth; et al.; "ESPEN Guidelines for Nutrition in Liver Disease and Transplantation"; Clinical Nutrition 1997; 16; pgs. 43-55
AO	O. Selberg, et al.; "Identification of High-and Low-Risk Patients Before Liver Transplantation: A Prospective Cohort Study of Nutritional and Metabolic Parameters in 150 Patients" Hepatology 1997; 25; pgs. 652-657
AP	J. Greve, et al.; "Bile Acids Inhibit Endotoxin-induced Release of Tumor Necrosis Factor by Monocytes: an <i>in Vitro</i> Study" Hepatology 1989; 10(4) pgs. 454-458
AQ	Y.Hori et al.; "Protective Effect of the Intravenous Administration of Ursodeoxycholic Acid Against Endotoxemia in Rats with Obstructive Jaundice" Surg Today, 1997; 27; pgs 140-144
AR	C. Lu et al.; "Efficacy of Ursodeoxycholic Acid in the Treatment of Patients with Chronic Hepatitis C" Journal of Gastroenterology and Hepatology 1995;10; pgs. 432-437
AS	A. Anker et al.; "Elevated Soluble CD 14 Receptors and Altered Cytokines in Chronic Heart Failure"; Am. J Cardiol 1997; 79; pgs. 1426-1430

EXAMINER:**DATE CONSIDERED:**

- **EXAMINER:** Initial if Reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformation and not considered, include copy of this form with next communication to applicant.
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